

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kristin Feeley et al. Art Unit : 3763
Serial No. : 10/786,021 Examiner : Christopher Koharski
Filed : February 26, 2004 Conf. No. : 2923
Title : ANTIMICROBIAL AGENT DELIVERY SYSTEM

Mail Stop Appeal Brief - Patents

Commissioner for Patents
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REPLY BRIEF

Pursuant to 37 C.F.R. § 41.41, Appellant responds to the Examiner's Answer as follows.

Regarding the combination of Suyeoka and Utterberg, the Examiner stated, for the first time, on page 4 of the Examiner's Answer, that Utterberg teaches "would the device rod to remain sterile during insertion into the patient for reduced infection". The Examiner also stated, for first the first time, on page 7 of the Examiner's Answer, that "it would have been an obvious modification to Suyeoka to add an anti-microbial agent to the intervention device in order to maintain sterility of the intervention device after being placed into the body or during insertion even though a sheath is already present on the device".

But, Suyeoka's device already remains sterile by a sheath (see, e.g., Suyeoka, col. 1, lines 74-col. 2, line 4), so the motivation asserted by the Examiner to combine Utterberg with Suyeoka to have Suyeoka's device "remain sterile" does not exist. Appellant disagrees that it would have been obvious to add anti-microbial agent to Suyeoka's device even though the sheath is already present. Appellant contends that the Examiner did not provide proper legal reasoning for why it would have been obvious to add the anti-microbial agent when the device is already kept sterile by the sheath.

Regarding the combination of Suyeoka and Hall, the Examiner stated, for the first time, on page 4 of the Examiner's Answer, that the motivation would have been in order to provide the shield of Suyeoka with enhanced sterility "by allowing controlled removal of the sheath due to the perforations". The Examiner also stated, for the first time, on pages 8 to 9 of the Examiner's Answer, that "the object of Hall et al. is to provide a guiding sheath that can be peeled away by a perforated slot but yet maintain stability during insertion. Therefore it would have been an

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obvious modification to Suyeoka to add perforations or substitute the continuous slot of Suyeoka for the perforated slot of Hall et. Al in order to allow for a removal of the sheath but yet maintain the integrity of the sheath during insertion and thus enhancing the sterility of the device".

But, Hall does not disclose (and would not have made obvious) that his sheath is used for enhancing sterility, let alone enhancing sterility "by allowing controlled removal of the sheath due to the perforations", as asserted by the Examiner. Accordingly, there would not have been the motivation as stated by the Examiner to combine Suyeoka and Hall. To the contrary, one skilled in the art would not have tried to combine the references because the inclusion of Hall's perforation into Suyeoka's sheath would have destroyed the intended use of Suyeoka's sheath, which is explained as follows.

Suyeoka's shield (part of the sheath) includes a continuous slit with a large slot and a small slot. (Id., col. 3, lines 37-48 and Figs. 2 and 8.) The large slot can lock a needle thumb tag and thus immobilize the needle in the shield so that a catheter fin can be forced forward into the small slot in the shield to advance the catheter into the vein, after which the catheter can be released from the needle and remain in the vein. (See, e.g., id., col. 4, lines 11-42, col. 5, line 55-col. 6, line 12, and Figs. 1, 2, 7 and 8.) It is therefore apparent that, besides maintaining sterility, the shield is also used to sustain the force to which it is subjected under its use conditions, and the slots of varying width are specifically arranged to allow for the intended use of the device. The shield of Suyeoka is not intended to be peeled off, and if peeled off, Suyeoka's device would not work in its intended manner. Thus, after reading Suyeoka, it would not have been obvious to one skilled in the art to modify Suyeoka to replace his continuous slit and slots with Hall's perforated longitudinal partition with an opening that facilitates peeling of the shield, at least because that person would realize that such a modification to Suyeoka's device could result in a device that did not work in the manner disclosed by Suyeoka.

Even if one skilled in the art had somehow wanted to try to modify Suyeoka's device, that person would not have considered Hall, and, even if that person had considered Hall, the person would not have combined Hall with Suyeoka in the manner indicated by the Examiner.

For these reasons, and the reasons stated in the Appeal Brief, Appellant submits that the final rejection should be reversed.

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Respectfully submitted,

Date: September 25, 2008

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